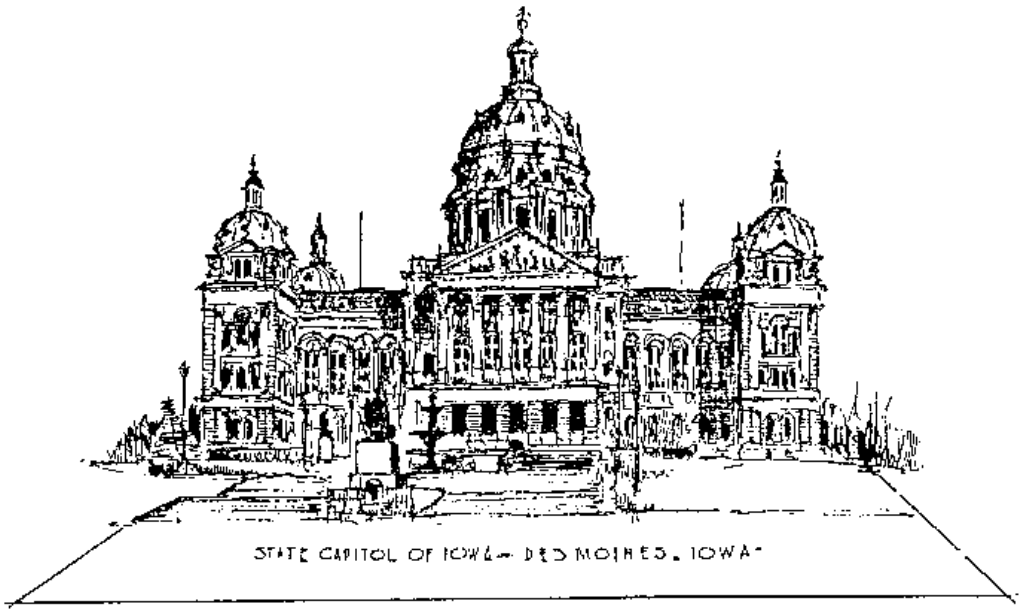
IOWA DEPARTMENT OF PUBLIC HEALTH

SPECIAL NUCLEAR MATERIAL LICENSES FOR LESS THAN CRITICAL MASS QUANTITIES REGULATORY GUIDE



Iowa Department of Public Health
Bureau of Radiological Health
Radioactive Materials Section
Lucas State Office Building, 5th Floor
321 East 12th Street
Des Moines, Iowa 50319-0075

IDPH REGULATORY GUIDE FOR SPECIAL NUCLEAR MATERIAL OF LESS THAN CRITICAL MASS QUANTITIES

REGULATORY GUIDE FOR
SPECIAL NUCLEAR MATERIAL OF LESS THAN
CRITICAL MASS QUANTITIES

1. INTRODUCTION

1.1 PURPOSE OF GUIDE

This guide describes the type of information needed to evaluate an application for a specific license for receipt, possession, use, and transfer of special nuclear material. It is intended for applicants requesting authorization to possess and use up to 2,000 grams of plutonium, total, as sealed plutonium-beryllium neutron sources, and any special nuclear material in quantities and forms not sufficient to form a critical mass.

Activities that involve the receipt, possession, use, and transfer of special nuclear material in quantities and forms sufficient to form a critical mass are not within the scope of this guide.

1.2 APPLICABLE REGULATIONS

Regulations pertaining to by-product material are found in Chapters 38, 39, and 40 of the Radiation Machines and Radioactive Materials Rules. You may go to www.idph.state.ia.us and click on Health Protection and Environmental Health. Follow the links to the Bureau of Radiological Health. The regulatory guides can be found by further following the links to Radioactive Materials.

The information in this guide is not a substitute for training in radiation safety or for developing and implementing an effective radiation safety program. You should carefully study this guide and all the regulations identified in the Iowa Rules and should then complete the application form, IDPH Form 299-0514. The IDPH may request additional information when necessary to provide reasonable assurance that the applicant has established an adequate radiation protection.

1.3 AS LOW AS REASONABLY ACHIEVABLE (ALARA) PHILOSOPHY

Paragraph 641-40.1(3) states "...Every reasonable effort should be made to maintain radiation exposures and releases of radioactive material in effluents to unrestricted areas as low as is reasonably achievable (ALARA)." As an applicant, you should consider the ALARA philosophy in the development of work plans involving radioactive materials.

The success of an ALARA program depends on the cooperation of each person who works at your facility. Management should make a formal policy commitment to the ALARA philosophy and implement that commitment with adequate resources.

The Radiation Safety Officer (RSO) and management are required to audit the by-product material program to ensure the continued safe use of by-product material. The RSO is also responsible for the day-to-day operations of the radiation safety program.

A model ALARA management program is contained in Appendix A to this guide. Applicants are required to consider the ALARA philosophy in the development of plans for radioactive materials.

2. FILING AN APPLICATION

You should apply for a license by completing form 229-0514, "Application for Radioactive Materials License." You should complete Items 1 through 5, and 14/15 on the form itself. For Items 6 through 12, submit the required information on supplementary pages. Identify each sheet or document with the item number on the application. All typed papers, sketches, and drawings, should be on 8 1/2 x 11-inch paper to facilitate handling and review, if possible. If larger drawings are necessary, fold them to 8 1/2 x 11 inches. You should complete all items in the application in enough detail for the IDPH to determine that your equipment, facilities, training, experience, and radiation safety program are adequate to protect the health and safety of the public as well as your employees.

Please note that license applications are available for review by the general public in the IDPH offices. Do not submit proprietary information unless necessary. If submittal of such information is necessary, please clearly specify the proprietary information. Failure to do so may result in disclosure of propriety information to the public or substantial delays in processing your application.

Do not submit personal information about your individual employees unless it is necessary. For example, the training and experience of individuals should be submitted to demonstrate their ability to manage radiation safety programs or to work safely with radioactive materials. Home addresses and home telephone numbers should be submitted only if they are part of an emergency response plan. Dates of birth, social security numbers, and radiation dose information should be submitted only if specifically requested by IDPH.

Retain a copy of your application because the license will be issued based on the statements and representations in your application and any supplements to it as well as the requirements in the regulations. The statements and representations become enforceable as if they were regulations

3. CONTENT OF APPLICATION

This portion of the guide explains, item by item, the information requested on IDPH Form 229-0514. The appendices to this guide serve to

- provide additional information on certain subject areas;
- provide a model procedure the applicant may adopt in response to an item on the application form; or
- provide an outline the applicant may use to develop a procedure for review by the IDPH staff.

If you have specific questions after careful review of this guide, contact the IDPH material licensing staff at Iowa Department of Public Health, Radioactive Materials Section, Lucas State Office Building, 5th Floor, 321 East 12th Street, Des Moines, Iowa 50319-0075, or call 515-281-3478.

ITEM 1.a. -- APPLICANT'S NAME AND MAILING ADDRESS

The applicant should be the corporation or other legal entity applying for the license.

The address specified here should be your mailing address for correspondence. This may or may not be the same as the address at which the material will be used as specified in Item 1.b.

ITEM 1.b. -- LOCATIONS OF USE

You should specify each location of use by the street address, city, and state or other descriptive address (such as 5 miles east on Highway 10, Anytown, Iowa) to allow us to easily locate your facilities. A post office box address is not acceptable. If by-product material is to be used at more than one location, you

must give the specific address of each location. In items 6 through 12 of the application, describe the intended use and the facilities and equipment at each location.

ITEM 2. -- PERSON TO BE CONTACTED ABOUT APPLICATION

You should provide the name and telephone number of the individual who knows your proposed radioactive materials program and can answer informational questions only about the application. This individual, usually the RSO or a principal user of radioactive materials, will serve as the point of contact during the review of the application and during the period of the license. If this individual is not your full-time paid employee, specify your relationship with this individual. Notify the IDPH if this individual changes. Unless the contact person is the RSO, a contact change is for information only. It would not be considered an application for a license amendment.

Any requests from the IDPH concerning additional commitments, procedures, or for changes to the application will be addressed to the CEO or President with a copy to the RSO. The CEO can designate a different person if the authorization to make commitments on behalf of the licensee if the CEO or President provides that authorization in writing to IDPH.

ITEM 3. -- LICENSE INFORMATION

For a new license, amendment to a license or renewal of an existing license, check the appropriate block. Provide the license number where indicated for amendments or renewals.

ITEM 4. -- INDIVIDUAL USERS -- THEIR TRAINING AND EXPERIENCE

A resume of the training and experience of each person who will directly supervise the use of material or will have radiological safety responsibilities should be submitted. The resume should include the type of training (e.g., on-the-job or formal course work), the location where the training was received, and the duration of the training. Training should include subjects such as (1) principles and practices of radiation protection, (2) radioactivity measurements, standardization, and monitoring techniques and instruments, (3) mathematics and calculations basic to the use and measurement of radioactivity, and (4) biological effects of radiation. The description of the actual use of radioactive materials or equivalent experience should include the specific isotopes handled, the maximum quantities of materials handled, where the experience was gained, the duration of experience, and the type of use. The qualifications, training, and experience should be commensurate with the proposed use of the material requested in the application.

ITEM 5. -- RADIATION SAFETY OFFICER (RSO)

State the name and title of the person designated by, and responsible to, the applicant's management as RSO. If the RSO is not one of the proposed authorized users, submit a complete description of the individual's training and experience. The RSO must be a full-time employee of the licensee. Even if you employ a consultant to assist the RSO, you are still responsible for the radiation safety program as required by the license.

The RSO needs independent authority to stop operations that are considered unsafe. The RSO also needs sufficient time and commitment from management to fulfill certain duties and responsibilities to ensure that radioactive materials are used only by authorized individuals and in a safe manner. The RSO’s duties and responsibilities should include those areas listed in Appendix B or its equivalent.

ITEM 6. -- RADIOACTIVE MATERIAL

The special nuclear material requested should be identified by isotope; chemical or physical form; activity in curies, millicuries, or, microcuries; and mass in grams. Specification of isotope should include principal isotope and significant contaminants. Major dose-contributing contaminants present or expected to build up are of particular interest. For example, the quantity of Plutonium-236 present in Plutonium-238 should be specified.

Possession limits requested should cover the total anticipated inventory, including stored materials and waste.

If the application is for a sealed source or plated source, the special nuclear material content and manufacturer's name and model number of each sealed or plated source should be specified. If a sealed source will be used in a device (holder, gage, analyzer, etc.), the manufacturer's name and model number of the device should be identified. Each source should be keyed to the specific devices used with it.

You should indicate the material that is being irradiated (e.g., foils, salts, etc.). Estimate the maximum amount of activity for the activated isotopes. Your license will include authorization for small quantities of these isotopes. If you are irradiating loose material, you must address area surveys. See Appendix D of this guide.

ITEM 7. -- PURPOSE

The operations for which the special nuclear material will be used and a general plan for carrying out the activity should be described. This information should be specified for each location where the special nuclear material will be used. Each individual operation should be described. The purpose of this descriptive information is to enable the IDPH to determine that the special nuclear material will be used for activities permitted under the IDPH's regulations and the Atomic Energy Act of 1954, as amended.

ITEM 8. -- INDIVIDUALS RESPONSIBLE FOR RADIATION SAFETY PROGRAM

Submit a description or chart of the overall organization pertaining to the radioactive materials program, which specifies the name and title of each individual who has responsibility for management or supervision of the program.

Items 9. Through 12.

Your response to these items should be:

- You will follow the model procedure in Appendix __ in the IDPH Regulatory Guide For Special Nuclear Material of Less Than Critical Mass Quantities;
- You have enclosed your procedure for review; or
- The notation "NA" for "not applicable."

Before you respond to an item, read the introductory paragraphs of the referenced appendix. Your response to Items 9 through 12 should run consecutively on one or more sheets. Lengthy responses should be appended as attachments.

If you edit a model procedure solely to name specific individuals, equipment by serial number, room numbers, or other site-specific information, there is no need to submit that procedure for review. Procedures should allow for replacement of identical equipment and personnel.

ITEM 9. -- TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS

Describe your training program for individuals who work near radioactive material described in Item 6.a. See Appendix C of this guide.

ITEM 10.1. -- FACILITIES AND EQUIPMENT

Submit an annotated drawing of the room or rooms and adjacent areas where by-product material will be used or stored. Append it as ATT 10.1. Note the following:

1. The number, type, and length of remote handling devices.
2. Storage containers and facilities. Consideration of both shielding and security of materials should be indicated.
3. Containers, devices, protective clothing, auxiliary shielding, general laboratory equipment, air sampling equipment, etc., actually employed in the daily use of material. Shielding and containment provision for loose materials designed to minimize personnel exposure should be described.
4. Physical plant, laboratory, or working area facilities. A description of all fume hoods, glove boxes, waste receptacles, special sinks, ventilation and containment systems, effluent filter systems, including the design specifications and capabilities of these systems, should be included. All processing, work, and change areas should be described. Applications for chemical or physical processing operations should include a description of the controls for fire prevention and the fire-fighting equipment available. Sketches showing laboratory or plant arrangements and the nature and-use of areas adjacent to areas in which special nuclear materials will be processed should be submitted.
5. Means of preventing entry into high radiation areas.
6. Means of preventing unauthorized use or removal of licensed material.

ITEM 10.2. -- RADIATION DETECTION INSTRUMENTS

Specify for each radiation detection instrument the following:

1. The manufacturer's name and model numbers.
2. The number of each type of instrument available.
3. The type of radiation detected (alpha, beta, gamma, or neutron).
4. The sensitivity range (mR/hr, neutrons per second, or counts per minute).
5. The window thickness in mg/cm^2.
6. The type of use for each instrument should be specified. The type of use would normally be monitoring, surveying, assaying, or measuring.
7. Frequency of calibration. Instruments must be calibrated annually and after servicing or repair. Electronic calibrations alone are not acceptable. Battery changes are not considered “servicing.” Quantitative measuring instruments used to maintain the adequacy of containment and contamination control such as those used for measuring leak tests, air, effluent, bioassay, work area, and equipment contamination samples are usually calibrated prior to each use.

If you are using an outside contractor to calibrate your survey instruments, provide the name, address, and license number of the company or individual. If you are calibrating your own instruments, please request the specific regulatory guide for calibrating instruments from the IDPH.

ITEM 11. -- RADIATION SAFETY PROGRAM

You, as the licensee, are responsible for the conduct of your radiation safety program and for all actions of your employees. The responsibilities and duties of management, any radiation safety committees, radiation safety officers, and users should be clearly established.

ITEM 11.1 -- PERSONNEL MONITORING

Review 641-40.37(136C).

Describe the personnel monitoring equipment (film badge, thermoluminescent dosimeters, or optically stimulated dosimeters (OSD) to be used, including the type of radiation monitored (beta, gamma, or neutron) and whether the monitoring is to evaluate whole body or extremity exposure. Identify the range, and frequency of reading, maintenance and calibration. Specify the name and address of the company who will provide the dosimeter service.

Review 40.27, radiation dose limits to the public. Students are considered the public for this license. You must figure possible dose to the students and provide procedures to maintain public dose limits. If your calculations do not indicate that additional precautions for the students are needed, submit your calculations and documentation.

ITEM 11.2 -- RADIATION SURVEY PROGRAM

A survey is defined as an evaluation of the radiation hazards incident to production, use, release, disposal, or presence of radioactive materials. Evaluation includes a physical survey of the location of materials and equipment and measurements of levels of radiation or concentrations of radioactive material present in air, water, or other materials and on surfaces. Describe the types, methods, and frequency of surveys according to the nature and complexity of your special nuclear material program. You may use Appendix D as a guide.

1. For operations involving only sealed sources, a survey program should include evaluation and/ or measurement of gamma and neutron radiation levels for storage and use areas. When sources are used in devices having "on" and "off" positions, both positions should be evaluated at the time of installation. Supplemental surveys should be performed following any changes in operation, shielding, use, or location of the device.

2. For operations involving materials in forms other than as sealed sources, the survey program should also be designed to monitor the adequacy of containment and contamination control. Include air-sampling, bioassays, monitoring effluent releases, and surveys to evaluate alpha contamination of personnel, work areas, and equipment.

    a. The specification of an air-sampling program should include the areas where samples will be taken, the frequency of sampling, the relationship to the processing or maintenance phase, and orientation of sampler with respect to workers' breathing zones. The type of assays that will be performed to evaluate air samples and the methods used to relate results to actual personnel exposures should be described.

    b. The effluent monitoring program for releases to unrestricted areas should encompass all airborne and liquid releases. Calculation evaluations should be supplemented by stack monitoring appropriate for the planned and potential releases.

c. The survey program for evaluating alpha contamination of personnel and plant surfaces should include provisions for monitoring protective clothing, hands, and feet of workers and/or students leaving restricted areas before breaks and at the end of shifts. Evaluation (alpha and/or gamma levels) of gloves or other protective clothing, equipment, or tools required during processing should be described. Surface contamination evaluation should include unrestricted areas such as lunchrooms, offices, etc. The survey program to monitor cleanup efforts for work areas where dust or loose materials are produced or spread should be described. Reasonable efforts should be made to remove all residual contamination. Acceptable limits of fixed and removable contamination for facilities in restricted areas should be set.

3. Acceptable limits of fixed and removable contamination for facilities and equipment in unrestricted areas and for release for unrestricted use should be set. For example, after reasonable effort to remove all residual contamination, if maximum alpha levels are 300-dpm/100 cm^2 or less and the average is 100-dpm/100 cm^2 or less, unrestricted use is permissible. **However, removable alpha contamination cannot exceed 20-dpm/100 cm^2.** These guidelines apply to all special nuclear material except mixtures of the naturally occurring isotopes of uranium (U-234, U-235, U-238) for which the levels may be a factor of 5 higher.

4. A survey program for pilot studies and initial phases of a full-scale production operation needed for evaluating and verifying actual hazards may be more extensive than the survey program that may be appropriate for the day-to-day program. Provisions for the evaluation of all changes in operation should be made.

ITEM 11.3 -- ORDERING AND RECEIVING

Procedures for ordering materials, receiving materials, notifying responsible persons upon receipt, and opening packages should be submitted. Depending on the quantity of radioactive material contained and its form, monitoring of packages may be required upon receipt.

ITEM 11.4 -- LEAK TESTING

Plutonium-beryllium sealed neutron sources and certain plutonium gamma sources are required by license condition to be tested for leakage and contamination at intervals not to exceed 6 months. Sealed sources designed as alpha sources and other plutonium sources must be tested at intervals not to exceed 3 months. When the supplier does not certify that such tests have been performed within the appropriate interval, the sources are not to be used until leak tested. The test sample should be taken from the source or from appropriate accessible surfaces of the device in which the sealed source is permanently mounted or stored where contamination could appear if the source were defective. Any leaking sources must be withdrawn from use and provision for decontamination, repair, or disposal should be made.

The options for leak testing are:

1. Engage the services of a consultant or commercial facility to take samples, evaluate the samples, and report the results to you.
2. Use a commercial leak-test kit. You take the smear and send the smear to the kit supplier, who reports the results to you.
3. Perform the entire leak-test sequence yourself, including the smears and measurement.

For Option 1, specify the name, address, and license number of the consultant of commercial organization.

For Option 2, specify the kit model number and the name, address, and license number of the kit supplier. In your application, you should state that the individuals specified in Item 4 who are responsible for your radiation safety program will take the test samples. Commit to Appendix E.1.

For Option 3, indicate how the test sample will be taken. Specify the instrumentation that will be used for measurement. An instrument capable of making quantitative measurements should be used. Hand-held survey meters will not normally be considered adequate for these measurements. Include a sample calculation for conversion of the measurement data to microcuries. You should also specify the individual who will make the measurement and his or her qualifications. The individual should have prior experience in making quantitative measurements, and this experience should be documented in your application. Commit to Appendix F or submit your own procedures.

ITEM 11.5 -- OPERATING AND EMERGENCY PROCEDURES

You should state on your application that you will provide the operating and emergency procedures to each person who uses the device and that they will be posted in all laboratory or work areas where radioactive materials are used. Submit the detailed operating and emergency procedures to the IDPH for review. You should cover these topics in your procedures:

1. Use of personnel monitoring.
2. Use of the radioactive material. Systematic procedures to follow.
3. Storage of the material -- See the commitment in Item 10.
4. Emergency procedures -- These instructions should describe immediate action to be taken in case of an emergency in order to prevent release of radioactive material or additional contamination of work areas and personnel. Examples of emergency procedures are turning off the ventilation system, evacuation of the area, reentry, procedures for containment of spills, etc. The instructions should specifically state the names and telephone numbers of responsible persons to be notified.

ITEM 11.6. -- RECORD MANAGEMENT

Refer to 641-40.80(136C) through 40.90(136C) Procedures for maintaining records of surveys; inventories; personnel exposures; receipt, use, and disposal of materials; etc., should be described. Persons responsible for keeping and reviewing records should be identified.

ITEM 11.7. -- ANNUAL AUDIT OF RADIATION SAFETY PROGRAM

The annual audit is required by 40.10(3). This will be reviewed during inspections.

ITEM 11.8. -- INVENTORIES

State that you will conduct inventories at intervals not to exceed 6 months to account for all radioactive material received and possessed under your license. You should maintain records of the inventories for at least 3 years from the date of the inventory, and should include the radionuclide and amount of material in each isotope. For sealed sources, include the manufacturer's name, model number and serial number of each source, location of each source, and date of the inventory.

ITEM 12 -- WASTE DISPOSAL

1. Wastes generated as a result of operations involving special nuclear material must be disposed of safely. Such wastes may include items such as contaminated tools, gloves, clothing, absorbent materials, filters, resin columns, decontamination solutions, or process wastes (see 641-40.70(136C)).

2. Wastes that are soluble or readily dispersible in water may be disposed of via the sanitary sewer system subject to monthly concentration limits specified in 641.40.72(136C).

3. The most commonly used method of disposal is transfer to a commercial firm licensed to accept such wastes. In dealing with such firms, prior contact is recommended to determine specific services provided.

4. Other methods of disposal may be considered and justified on a case-by-case basis. The information specified in 641-40.71(136C) should be submitted to support a request for any alternate methods of disposal. This information should include the quantities and kinds of materials, the levels of radioactivity, a description of the manner and conditions of disposal, an evaluation of environmental considerations, and the control procedures.

5. Indicate how each waste will be disposed.

ITEM 13. -- LICENSE FEES

1. An application fee paid in full is required by 641-38.8(2) for all new licenses and amendments. Fee information is available in the above rule or our web site at www.idph.state.ia.us. An application received without a fee or with an inadequate fee may be returned to you. Fees for processed applications are not refundable. Make check or money order payable to the IDPH.

2. An annual fee will be assessed based on the license category and is due by September 1st of each year. IDPH sends a billing invoice in July of each year for the annual fee.

3. Review 39.4(26) “Financial Assurance and Recordkeeping for Decommissioning.” Submit financial assurance as described or provide information that exempts the facility.

ITEM 14, 15 -- CERTIFICATION

A senior partner, the president, director or chief executive officer must sign the application. Identify the title of the office held by the individual who signs the application.

If the senior partner, president, director, or chief executive officer wishes another person other than himself to sign the application, a delegation of authority must be enclosed. The delegation of authority should state that the person signing the application has authority to commit the facility to the conditions of the application and any amendments submitted later.

4. AMENDMENTS TO LICENSE

A licensee must receive a license amendment before changing the scope of the program such as changing the Radiation Safety Officer or adding to the staff of authorized users. See 641-39.4(35). An application for an amendment must be filed either on IDPH Form 299-0514 or as a letter. The person delegated in Item 14/15 must sign the request. The appropriate fee must be included.

You may not place into effect any amendment until receiving written verification from the IDPH that the amendment has been approved.

5. RENEWAL OF LICENSE

An application for the renewal of a license should be filed at least 30 days before the expiration date. This will ensure that the license does not expire before the final action on the application has been taken by the IDPH as provided for in paragraph 641-39.4(34). The application for the renewal should not reference material that was previously submitted.

If you do not wish to renew your license and cannot dispose of all the licensed radioactive material in your possession before the expiration date, you must request a license renewal for storage only of the radioactive material. The renewal is necessary to avoid violating IDPH regulations that do not allow you to possess licensable material without a valid license.

6. IMPLEMENTATION

The information in this regulatory guide is guidance, not requirement. The IDPH reviews each application to ensure that users of by-product material are capable of complying with IDPH's regulations. This guide provides one set of methods approved by the IDPH for meeting the regulations and represents the minimum acceptable standards.

7. INSPECTIONS

IDPH conducts initial inspections of new radiological programs between six months and one year after licensed material is received and operations have begun. Subsequent routine inspections of licenses are normally scheduled after the initial inspection. The routine inspections are scheduled at intervals corresponding to frequency, which is indicated in the IDPH Radioactive Materials Fee Schedule.

APPENDIX A

MODEL PROGRAM FOR MAINTAINING OCCUPATIONAL RADIATION EXPOSURE ALARA

You may use the text as it appears here, saying on your application, "We will establish and implement the model ALARA program that was published in Appendix A to the IDPH Regulatory Guide For Special Nuclear Material of Less Than Critical Mass Quantities." Submit a signed copy of section 5 of this appendix.

If you prefer, you may develop your own ALARA program for IDPH review. If you do so, you should consider for inclusion all the features in the model and carefully review the requirements of Iowa Rules. Say on your application, "We have developed an ALARA program for your review that is appended as Appendix A," and submit your program and a signed copy of section number 6 of this appendix.

ALARA PROGRAM

1. MANAGEMENT COMMITMENT

   a. We, the management of this facility, are committed to the program described herein for keeping individual and collective doses as low as is reasonably achievable (ALARA). In accord with this commitment, we hereby describe an administrative organization for radiation safety and will develop the necessary written policy, procedures, and instructions to foster the ALARA concept within our institution.

   b. We will perform a formal annual review of the radiation safety program, including ALARA considerations. This will include reviews of operating procedures and past dose records, inspections, etc., and consultations with the radiation safety staff or outside consultants.

   c. Modifications to operating and maintenance procedures and to equipment and facilities will be made if they will reduce exposures unless the cost, in our judgment, is considered to be unjustified. We will be able to demonstrate, if necessary, that improvements have been sought, that modifications have been considered, and that they have been recommended but not implemented, and we will be prepared to describe the reasons for not implementing them.

   d. In addition to maintaining doses to individuals as far as below the limits as is reasonably achievable, the sum of the doses received by all exposed individuals will also be maintained at the lowest practicable level. It would not be desirable, for example, to hold the highest doses to individuals to some fraction of the applicable limit if this involved exposing additional people and significantly increasing the sum of radiation doses received by all involved individuals.

2. RADIATION SAFETY OFFICER COMMITMENT

   a. Annual and Quarterly Review

      (1) Annual review of the radiation safety program. The RSO will perform an annual review of the radiation safety program for adherence to ALARA concepts. Reviews of specific methods of use may be conducted on a more frequent basis.
      (2) Quarterly review of occupational exposures. The RSO will review at least quarterly the external radiation doses of authorized users and workers to determine that their doses are ALARA in accordance with the provisions of section 4 of this appendix.

   b. Education Responsibilities for ALARA Program

The RSO will schedule briefing and educational sessions to ensure that authorized users, workers, and ancillary personnel who may be exposed to radiation will be instructed in the ALARA philosophy. They should also be informed that management and the RSO are committed to implementing the ALARA concept.

c. Cooperative Efforts for Development of ALARA Procedures

Radiation workers will be given opportunities to participate in formulating the procedures that they will be required to follow.

(1) The RSO will be in close contact with all users and workers in order to develop ALARA procedures for working with radioactive materials.
(2) The RSO will establish procedures for receiving and evaluating the suggestions of individual workers for improving health physics practices and will encourage the use of those programs.
(3) Workers will be instructed in recourses available if they feel that ALARA is not being promoted on the job.

d. Reviewing Instances of Deviation from Good ALARA Practices:
The RSO will investigate all known instances of deviation from good ALARA practices and, if possible, will determine the causes. When the cause is known, the RSO will implement changes in the program to maintain doses ALARA.

3. AUTHORIZED USERS COMMITMENT

a. New methods of Use Involving Potential Radiation Doses

(1) The authorized user will consult the RSO during the planning stage before using radioactive materials for new uses.
(2) The authorized user will review each planned use of radioactive materials to ensure that uses will be kept ALARA. Trial runs may be helpful.

b. Authorized User's Responsibility to Supervised Individuals

(1) The authorized user will explain the ALARA concept and the need to maintain exposures ALARA to all supervised individuals.
(2) The authorized user will ensure that supervised individuals who are subject to occupational radiation exposure are trained and educated in good health physics practices and in maintaining exposures ALARA.

4. ESTABLISHMENT OF INVESTIGATIONAL LEVELS IN ORDER TO MONITOR INDIVIDUAL OCCUPATIONAL EXTERNAL RADIATION DOSES[1]

This institution hereby establishes investigational levels for occupational external radiation doses which, when exceeded, will initiate review or investigation by the RSO. The investigational levels that we have adopted are listed in Table 1. These levels apply to the exposure of individual workers.

[1] IDPH emphasizes that the investigational levels in this program are not new dose limits but serve as check points above which the results are considered sufficiently important to justify investigations.

TABLE 1 INVESTIGATIONAL LEVELS		
	Investigational Levels (millirems per month)	
	Level I	Level II
1. Total Dose Equivalent: whole body; head and trunk; active blood-forming organs; or gonads	200	400
2. Skin of whole body, extremities	2000	4000
3. Lens of eyes	600	1200

The RSO will review and record on IDPH Form, "Current Occupational External Radiation Exposures," or an equivalent form (e.g., dosimeter processor's report) results of personnel monitoring not less than once in any calendar quarter as required by 641-40.100. The following actions will be taken at the investigational levels as stated in Table 1:

a. Personnel dose less than Investigational Level I.

   Except when deemed appropriate by the RSO, no further action will be taken in those cases where an individual's dose is less than Table 1 values for the investigational Level I.

b. Personnel doses equal to or greater than Investigation Level I but less than Investigational Level II.

   The RSO will review the dose of each individual whose quarterly dose equals or exceeds Investigational Level I and will report the results of the reviews to management as soon as completed. If the dose does not equal or exceed Investigational Level II, no action related specifically to the exposure is required. The RSO and management will, however, review each such dose in comparison with those of others performing similar tasks as an index of ALARA program quality.

c. Personnel dose equal to or greater than Investigational Level II.

   The RSO will investigate in a timely manner the causes of all personnel doses equaling or exceeding Investigational Level II and, if warranted, will take action. A report of the investigation and any actions taken will be presented to the management following completion of the investigation. The report should include a copy of the individual's Form IDPH 588-2834 “Occupational Exposure Record for Monitoring Period” and 588-2833 “Cumulative Occupational Exposure History” or its equivalent.

d. Re-establishment of investigational levels to levels above those listed in Table I.

In cases where a worker's or a group of workers' doses need to exceed an investigation level, a new, higher investigational level may be established with good ALARA practices. Justification for new investigational level will be documented.

The RSC will review the justification for and must approve or disapprove all revisions of investigational levels.

5. SIGNATURE OF CERTIFYING OFFICIAL[1] Sign and submit as part of Appendix A.

I hereby certify that this institution has implemented the ALARA Program as set forth above.

_____
Signature

_____
Name (Print or type)

_____
Title

[1] The person who is authorized to make commitments for the administration of the institution (e.g., CEO, president, etc.).

APPENDIX B

DUTIES AND RESPONSIBILITIES OF THE RADIATION SAFETY OFFICER (RSO)

You may use the following model procedure to make commitments for your RSO. If you follow the model procedure, you may say on your application, "We will establish and implement the model procedure for RSO that was published in Appendix B to the IDPH Regulatory Guide For Special Nuclear Material of Less Than Critical Mass Quantities."

You may develop your own procedure for review. If you do so, you should consider for inclusion all the features in the model and carefully review the requirements of the Iowa Rules. Say on your application, "We have developed an RSO procedure for your review that is appended as Appendix B", and submit your procedure.

MODEL PROCEDURE

The RSO is responsible for implementing the radiation safety program and ensuring that radiation safety activities are performed in accordance with approved procedures and regulatory requirements. The RSO's duties and responsibilities include:

1. Ensure that licensed material possessed by the licensee is limited to the kinds, quantities and forms listed on the license.
2. Ensure that individuals using the material are properly trained; designated by the RSO; have received refresher training at least annually; and are informed of all changes in regulatory requirements and deficiencies identified during annual audits or IDPH inspections.
3. Ensure that personnel monitoring devices are used as required. Ensure that exposure reports are reviewed in a timely manner.
4. Ensure that material is properly secured against unauthorized removal at all times when material is not in use.
5. Ensure that proper authorities are notified in case of accident, damage, fire, or theft.
6. Ensure that audits are performed at least annually to ensure that:
    a. The licensee is abiding by IDPH regulations and the terms and conditions of the license (e.g., periodic leak tests, inventories, use limited to trained, approved users),
    b. The licensee's radiation protection program content and implementation achieve occupational doses and doses to members of the public that are ALARA, and
    c. The licensee maintains required records with all required information (e.g., records of personnel exposure; receipt, transfer, and disposal of licensed material; user training) sufficient to comply with IDPH requirements.
7. Ensure that the results of audits, identification of deficiencies, and recommendations for change are documented, provided to management for review, and maintained for at least 3 years. Ensure prompt action is taken to correct deficiencies.
8. Ensure that audit results and corrective actions are communicated to all personnel who use licensed material (regardless of their location or the license under which they normally work).
9. Ensure that all incidents, accidents, and personnel exposure to radiation in excess of ALARA or Chapter 40 are investigated and reported to IDPH within the required time limits.
10. Ensure that licensed material is disposed of properly.
11. Ensure that the facility has up-to-date copies of IDPH's regulations, completing a review of new or amended IDPH regulations, and revising licensee procedures, as needed, to comply with IDPH regulations.
12. Ensure that the license is amended whenever there are changes in licensed activities, responsible individuals, or information or commitments provided to IDPH in the licensing process.

APPENDIX C

MODEL TRAINING PROGRAM
In addition to 641-40.111

The following guidance may be used to develop a training program. If you use the frequency and subject listings to develop your training program, you may say on your application, "We will establish and implement the model training program that was published in Appendix A to the IDPH Regulatory Guide For Special Nuclear Material of Less Than Critical Mass Quantities." You may use lectures, videos-taped presentations, or demonstrations, for example, as methods of training.

If you prefer, you may develop your own training program for review. If you do so, you should consider for inclusion all the features in the model program and carefully review the requirements of 641-40.111. Say on your application, "We have developed a training program for your review that is appended as Appendix C." Be sure to include the groups of workers, the method of their training, and the frequency of training.

It may not be assumed that prior occupational training, board certification, etc. have adequately covered safety instructions. Site-specific training should be provided for all workers. Ancillary personnel (e.g., clerical, housekeeping, security) whose duties may require them to work near radioactive material (whether escorted or not) need to be informed about radiation hazards and appropriate precautions. A training program that provides necessary instruction should be written and implemented.

MODEL PROGRAM

Personnel to be instructed:

1. All workers that might receive an occupational dose.
2. Ancillary personnel (e.g. clerical, housekeeping, security, students) whose duties may require them to work in the vicinity of radioactive material.

Frequency of instruction:

1. Before assuming duties with, or in the vicinity of, radioactive materials.
2. During annual refresher training.
3. Whenever there is a significant change in duties, regulations, or the terms of the license.

Instruction for individuals will include the following subjects in addition to 40.111:

1. Applicable regulations and license conditions.
2. Licensee's in-house work rules.
3. Locations where the licensee has posted or made available notices, copies of pertinent regulations, and copies of pertinent licenses and license conditions (including applications and applicable correspondence), as required by 641-40.110.
4. Question and answer period.
5. Record of date of program, subject and attendees.

APPENDIX D

MODEL PROCEDURE FOR AREA SURVEYS
in addition to 641-40.27

You may use the following procedure to perform area surveys. If you follow this procedure, you may say on your application, "We will establish and implement the model procedure for area surveys that was published in Appendix D to the IDPH Regulatory Guide For Special Nuclear Material of Less Than Critical Mass Quantities."

You may develop your own procedure for review. If you do so, you should consider for inclusion all the features in the model procedure and carefully review the requirements of 641-40.27. Say on your application, "We have developed survey procedures for your review that are appended as Appendix D" and submit your survey procedures.

MODEL PROCEDURE

Surveys will be repeated when quantity or type of radioactive material changes or changes occur in containment systems or methods of use.

AMBIENT DOSE RATE SURVEYS

1. Survey Areas -- Restricted Areas

    a. In areas where only small quantities of gamma-emitting radioactive material are processed (less than 200 microcuries at a time), survey monthly with a radiation detection survey meter.
    b. In sealed source storage areas, survey quarterly with a radiation survey meter.
    c. The wearer should survey protective clothing after use if significant contamination is possible. Contaminated clothing should be removed before leaving a restricted work area. Hands should be washed and surveyed. Personal clothing should also be surveyed before leaving the restricted areas. Any contamination above expected levels should be reported to the RSO.

2. Survey Areas -- Unrestricted Areas

    Quarterly surveys should be accomplished in areas
    - adjacent to restricted areas
    - through which radioactive materials are transferred
    - where radioactive material is temporarily stored before shipment

    More frequent surveys will be necessary if radiation levels are suspect.

REMOVABLE CONTAMINATION SURVEYS

Survey Areas:

Survey at least quarterly in any area where the potential for spreading contamination is likely to occur (e.g., cafeterias, snack bars, furniture, and equipment). Random wipe testing of floors alone is acceptable for most unrestricted areas. If such surveys reveal that radioactive contamination is being transferred out of restricted areas, immediate corrective action should be taken to eliminate such transfers. Surveys that are more frequent should be conducted until a trend of negative results is again established.

The wipe sample assay procedure should be sufficiently sensitive to detect the presence of 2000 dpm/100 cm^2 of removable contamination (200 dpm/100 cm^2 for isotopes of iodine). You must use a radioactive source with a known amount of activity to convert sample measurements (usually in counts per minute or cpm to disintegrations per minute or dpm).

Immediately notify the RSO if you find levels that exceed the established action levels. See Table K-1 below for guidance in establishing your action levels.

RECORDS

1. Records must include the information in 40.82 as well as actions taken in the case of excessive dose rates or contamination and follow-up survey information.

2. The RSO will review and initial the record at least monthly and promptly in those cases in which action levels were exceeded.

TABLE K-1

Recommended Action Levels in dpm/100 cm^2 for Surface Contamination

	P-32, Co-58, Fe-59, Co-60, Se-75, Sr-85, In-111, I-123, I-125, I-131, Yb-169, Au-198	Cr-51, Co-57, Ga-67, Tc-99m, Hg-197, Tl-201
1. Unrestricted areas, personal clothing	200	2,000
2. Restricted areas, protective clothing used only in restricted areas, skin	2,000	20,000

APPENDIX E

MODEL PROCEDURE FOR LEAK-TESTING SEALED SOURCES

You may use the following model procedure to leak-test sealed sources. If you follow the model procedure you may say on your application, "We will establish and implement the model procedure for leak-testing sealed sources that was published in Appendix (E.1 and/or E.2) to the IDPH Regulatory Guide For Special Nuclear Material of Less Than Critical Mass Quantities."

You may develop your own procedure for review. If you do so, you should consider for inclusion all the features in the model and carefully review the requirements of Iowa Rules. Say on your application, "We have developed a leak-test procedure for your review that is appended as Appendix (E.1 and/or E.2)," and submit your leak-test procedure.

E.1 - MODEL PROCEDURE FOR TAKING TEST SAMPLES

1. Make a list of all sources to be tested. This should include at least the isotope, the activity on a specified date, and the physical form.
2. If you will be testing sources stronger than a few millicuries, set out a survey meter, preferably with a speaker, so you can monitor your exposure rate.
3. Prepare a separate wipe sample for each source. A cotton swab, injection prep pad, filter paper, or tissue paper is suitable. Number each wipe so you will know for which source it is to be used. Samples should be taken as follows:
   a. For small sealed sources, it may be easier to wipe the entire accessible surface area. Pay particular attention to seams and joints. However, do not wipe the port of beta applicators.
   b. For larger sealed sources and devices (survey meter calibrator), take the wipe near the radiation port and on the activating mechanism.
   c. If you are testing radium sources, you should also check for radon leakage. Submerging the source in a vial of fine-grained charcoal or cotton for a day can do this. Then remove the source and analyze the absorbent sample as described below. A survey should be done to be sure that sources are adequately shielded during the leak-test period.

E.2 - MODEL PROCEDURE FOR ANALYZING TEST SAMPLES
(for Option 3 of Item 11.4)

The samples will be analyzed as follows:

1. Select an instrument that is sufficiently sensitive to detect 0.005 microcurie (185 Bq) for beta or gamma emitting radionuclides. For alpha emitting radionuclides, select an instrument that is sufficiently sensitive to detect 0.001 microcurie (37 Bq). For beta sources, a proportional flow counter, liquid scintillation counter, or thin-end-window GM survey meter may be appropriate. For gamma sources, a GM instrument or a sodium-iodide crystal with a ratemeter or scaler may be appropriate. Dose calibrators used in nuclear medicine are not sufficiently sensitive. For alpha emitting radionuclides, a zinc-sulfide scintillation detector with a ratemeter or scaler is appropriate.
2. To estimate the detection efficiency of the analyzer used to assay the wipe samples, assay a certified check source that has the same isotope as the sealed source. If one is not available, it will be necessary to use a certified check source with a different isotope that has a similar spectrum. If calculations demonstrate that the instrument is not sufficiently sensitive to detect 0.005 microcurie for beta or gamma emitters or 0.001 microcurie for alpha emitters, a different instrument must be used.
3. Assay the wipe sample. It must be in the same geometry relative to the detector as was the certified check source. Wipes of alpha emitting radionuclides should be dry and the exposed, single layer of the wipe material should face the detector.

4. Record the wipe sample in counts per minute. Then calculate and record the estimated activity in microcuries on the wipe sample.
5. Continue the same analysis procedure for all wipe samples.
6. If the wipe sample activity is 0.005 microcurie or greater for beta or gamma emitting radionuclides or 0.001 microcurie for alpha emitting radionuclides, notify the RSO. The source must be withdrawn from use to be repaired or disposed in accordance with IDPH rules.
7. Record model number and serial number (if assigned) of each source tested, radionuclide and estimated activity, measured activity of each test sample in microcuries, description of method used to test each sample, date of test, and signature of RSO. Maintain records for 5 years.

Revision	Section	Description
12/27/00	All	Format text. Changed address for Bureau of Radiological Health.
03/13/03	Section 1.2	Replace the website address of the IDPH rules and publications.
07/01/05	All	Changed address for the Bureau of Radiological Health
09/07/10	Sections 3.13 & 7	Removed references to renewal and inspection fees. Added reference to annual fee.